ASPECTS OF INFORMING AND OBTAINING CONSENT WHILE CONDUCTING TRIALS IN PULMONOLOGY AND PSYCHIATRY

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While obtaining voluntary informed consent from patients with chronic obstructive pulmonary disease (COPD), bronchial asthma and patients presenting with psychiatric symptomology who participate in clinical trials, it is necessary to remember not only about the rights and ethical standards, but also about an extremely vulnerable position of the participants due to their disease specificity. Changes in the mental status of the patients and principal problems of every patient need to be considered. In this article, the aspects of obtaining informed consent from patients with respiratory diseases such as bronchial asthma and COPD and those under psychiatric supervision are reviewed. Apart from general recommendations, every category of patients has its own specific features. Being aware of them will improve doctor-patient communication.

Key words: clinical trial, informed consent, vulnerable groups, bronchial asthma, chronic obstructive pulmonary disease, schizophrenia, depression

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АСПЕКТЫ ИНФОРМИРОВАНИЯ И ПОЛУЧЕНИЯ СОГЛАСИЯ ПРИ ПРОВЕДЕНИИ ИССЛЕДОВАНИЙ В ПУЛЬМОНОЛОГИИ И ПСИХИАТРИИ

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В клинических исследованиях, проводимых в группах пациентов с хронической обструктивной болезнью легких (ХОБЛ), бронхиальной астмой, а также у пациентов психиатрического профиля при получении добровольного информированного согласия необходимо помнить не только о правах и этических нормах, но и о том, что в данной процедуре принимают участие люди, находящиеся в крайне уязвимом состоянии в связи со спецификой каждого из заболеваний. В процессе получения информированного согласия у таких пациентов необходимо учитывать характерные для них изменения психологического статуса и принимать во внимание приоритетные проблемы каждого пациента. В этой статье рассмотрены аспекты получения информированного согласия у пациентов с заболеваниями респираторного тракта на примере бронхиальной астмы и ХОБЛ и у пациентов, находящихся под наблюдением врача психиатра. Каждая из категорий пациентов помимо общих рекомендаций имеет свои особенности, знания которых помогут в улучшении коммуникации между врачом-исследователем и пациентом.

Ключевые слова: клиническое исследование, информированное согласие, уязвимые группы, бронхиальная астма, хроническая обструктивная болезнь легких, шизофрения, депрессия

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Voluntary informed consent (VIC) is an important element of the system that guarantees compliance of medical experiments with ethical guidelines and observance of participants' rights. Every participant of a clinical trial (CT) should willfully and voluntarily provide the VIC [1, 2]. This can be a patient or healthy volunteer who receives a medicinal agent during the trial or stays in the control group [2–4].

In accordance with International Harmonized Rules of Clinical Trials (ICHGCP), obtaining a VIC is a process that allows patients to confirm their consent to participate in the clinical trial after acquisition of exhaustive data about all aspects of the trial. Consent is expressed by signing the VIC form which the patient has already read [5].

Those joining a clinical trial go through an obligatory process of giving VIC. It is a key component of any biomedical research which allows to observe participants' rights and ethical standards. When getting and documenting the VIC, a researcher should follow regulatory requirements, rules and ethical principles mentioned in the World Medical Association (WMA) Declaration of Helsinki.

Getting consent is rather burdensome and time-consuming both for researchers, and for participants [3]. Patients should be included in clinical trials only when they obtained information about participants' rights, examined scientific issue, research methodology, medicinal agent, course of treatment, potential risk and benefit, possible alternative treatment and potential shortcomings associated with research procedures [4]. The researchers should always do their best to record the process and obtain the VIC in writing.

While working with a patient, it is necessary to remember that the person is vulnerable due to the existing disease. In its turn, the perception of illness influences the internal disease pattern which is subjective for every patient and diagnosis.

VULNERABLE PARTICIPANTS OR PATIENTS

Vulnerable participants include persons or groups of persons who can't give spontaneous consent to or refuse from participation in the trial, and persons who are willing to participate in the trial because they are expecting certain advantages [1, 2]. The participants include people with severe and incurable diseases, subjects from rest homes, patients with medical emergencies, minors, those placed with foster parents and guardians, and people who are not capable of conscious consenting to clinical trials. Vulnerable patients also include those with mental disorders or those who can provide their consent under pressure; beggars and unemployed people, people belonging to national minorities, homeless persons, migrants and refugees; people who can probably wish to enter clinical trials due to high expectations [1, 2, 6].

SPECIFIC NATURE OF OBTAINING INFORMED CONSENT FROM PATIENTS WITH BRONCHIAL ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Patients with respiratory diseases are included into a separate vulnerable group.

The act of breathing is a vital process for a human life, as without this, it only takes several minutes for death to occur. Patients with bronchial asthma (BA) and chronic obstructive pulmonary disease (COPD) belong to a separate group. Their participation in clinical trials and procedure of getting informed consent have some specific features.

It is known that a chronic respiratory disease influences the mental status of a subject. First of all, this concerns patients with BA and COPD [6–8].

COPD imposes a burden represented by dyspnea to a different extent, but on a constant basis. The burden produces an effect on patient's physical and social activity which is most commonly decreased. Bad perception of the future and the feeling of hopelessness are developed. As a respiratory disease is progressing, dyspnea can even be more destructive, incapacitating and threatening, resulting in severe depression and anxiety [4]. In its turn, fear and anxiety can exacerbate dyspnea, result in hyperventilation symptoms and panic attacks, catching patients in a vicious circle and causing distress [7, 12].

During clinical trials, collaboration of doctors and patients, their involvement and readiness to participate, provision of feedback about the obtained treatment, therapy effect, occurrence of side symptoms and adverse events, and any changes observed in patients are important. The basis for successful conduction of a CT is formed when informed consent is obtained.

According to observations, patients know little about and are poorly informed of their disease [9]. During COPD aggravation, patients are commonly passive and wait for their symptoms to be relieved [10]. Under these circumstances, a medical investigator also has to increase patient awareness of the mechanism of pathological processes and existing possibilities to control the disease in order to improve the patient's personal responsibility.

A CT starts with obtaining informed consent. Proper communication with a patient is important. Good doctor-patient relationship means better adherence to treatment [11]. It has been shown in the MIRROR trial that patients with COPD are usually dishonest with their treating physician and medical personnel, whereas doctors may be not aware of the fact and underestimate it. Moreover, doctors and patients treat different symptoms in a different way. Thus, doctors pay more attention to dyspnea, whereas fatigue and pulmonary rales seem more important to patients [7]. It is necessary to remember that the patients have depression and increased anxiety.

In the majority of clinical trials, an informed consent form is a long document with a vast number of specific terms that can seem terrifying to a patient. When building a correct dialogue with a patient, it must be remembered that explaining the essence of a CT, basic principles and treatment process is an important and necessary link in communication with a patient.

It is obligatory that a patient should be informed of potentially related trial design, frequency of visits, and temporary and transport inconveniences. Patients should be aware that their time, occupation and things to do are just as important and prioritized as the clinical trial.

Duration of conversation is important while obtaining VIC from a patient with COPD. Patients tend to concentrate on the reasons for their disease and display surprise because they have the disease. The study doctor needs to be patient and show empathy.

Though in real life COPD and BA are referred to by one word 'asthma' and the two respiratory diseases are sometimes confused, patients significantly differ not only by mechanisms of abnormal process development, but also by psychological characteristics. As a consequence, a study doctor needs to remember about the specific traits when talking to the patient.

In a series of trials, strong and serial communications were discovered between asthma and anxiety disorders, in particular, panic disorders, panic attacks, generalized anxiety disorders, phobia, etc. [13]. Thus, according to Feldman, up to 45.0% of patients with asthma have different psychiatric diagnoses [14]; 63.0% of patients with asthma who requested urgent assistance due to acute exacerbation of an underlying disease demonstrated signs of anxiety disorder [15]. This is probably associated with a disturbing nature of asthma symptoms and their unexpectedness.

While obtaining VIC in patients with BA, it's necessary to find out which therapy — especially urgent therapy — can be used, and pay their attention to a lack of limitations while requesting medical aid during a clinical trial. A patient must be sure that he/she can obtain any kind of medical aid as soon as asthma symptoms are developed. A study doctor needs to establish a dialogue with the patient and necessarily inform the patient that feedback with a doctor is provided.

The peculiarity of obtaining informed consent within a clinical trial in patients with respiratory diseases consists in unwillingness to read a long and multipage document. A study doctor needs to read it together with the patient, pay his/her attention to all peculiarities of a certain trial, patiently explain all specific terms and complicated moments.

We should bear in mind that the majority of potential volunteers who visited the clinic have already taken a decision to participate in the clinical trial before informed consent was obtained [16]. In

practical terms, it means that the process of signing an informed consent form starts before possible participants get their hands on the consent. Prior information of volunteers is essentially the first step to obtaining informed consent [17].

Researches of new biological molecules cover most of recent clinical trials in respiratory diseases. The agents, and such terms as 'biological therapy', 'targeted therapy', 'monoclonal antibodies' are all new. This is the part where many questions related to obtaining informed consent arise. All complicated and intimidating terms need to be 'translated' into a simple and non-medical language. Patients are interested how the agents influence the immunity and, especially, 'decreased immunity'. Biological molecules used in respiratory medicine are targeted at principle inflammatory mediators produced in disease pathogenesis and suppress their action. When the mechanism of action is explained to the patients, they try to understand whether and how exactly the general immune response is changed; which possible risks occur during suppression of a molecule. In this respect, the term 'a monoclonal antibody' sometimes becomes intimidating. For a study doctor, the term is just about the way of obtaining a molecule, and the doctor doesn't pay attention to it. However, the patient hears a new term and can interpret it in his/her own way (is it about cloning?). So, an explanation is obligatory. During the explanation, we need to look at the patient's reaction to every scientific term and explain what it means with an accessible language.

The effect produced by biological therapy on genome and reproductivity is another question that needs to be discussed when informed consent is obtained. It is necessary to give examples of already available biological molecules and describe the experience of their safe use by pregnant and nursing women, if any, and by pediatric population. Examples of successful and long-term use of biological agents in other areas of medicine (rheumatology and oncology) can be useful.

Many patients with COPD and BA, especially those with a severe course, develop signs of encephalopathies, which are progressing as the disease becomes more severe [18]. It has been shown in the majority of trials that patients with COPD have significant cognitive disturbances in general or in such areas as cognition, memory and motor functions [19]. Chronic hypoxemia typical of severe respiratory diseases is one of the most important key mechanisms that can produce a negative effect on neuropsychological and cognitive indicators [20, 21]. While obtaining informed consent from these patients, it is sometimes necessary to repeat information several times and/or use different wording.

SPECIFIC NATURE OF OBTAINING INFORMED CONSENT FROM PSYCHIATRIC PATIENTS

Psychiatric patients belong to another group of patients who require special attention while consent is obtained. Disturbance of various functions resulting from mental disturbances raise a great number of questions about the possibility of taking informed consent from psychiatric patients. It should be noted that the legal term 'lack of legal capacity' doesn't always correlate with the term 'incapability' as far as the ability to take decisions goes. Thus, patients who are legally competent can become incapable during certain periods of time as far as assessment of risks and advantages and taking informed consent are concerned. The principal complexity for a study doctor is to understand correctly whether a patient is capable to take an informed decision or not.

Comparatively small amounts of data that can be taken as a reference value have been accumulated to this date. That's why researchers have to take decisions based on their personal experience.

The conducted trials have shown that patients with schizophrenia have a more disturbed ability to take decisions as compared with patients who have depression and general population [21, 22]. However, patients with schizophrenia include those who can take decisions just similar to people without mental disturbances. According to the research results published in 2000 [23], when the ability of patients with schizophrenia, schizoaffective disorders and healthy volunteers to take decisions was compared, patients with schizophrenia are less capable of taking decisions but with a larger spread of data present. Similar results were replicated multiple times [24–26].

Though many efforts were spent on searching psychopathological correlates of decision taking ability, it has been shown that the strongest predictor of this ability is represented by neuropsychological functioning [27–29]. There is a definite correlation between cognitive manifestations of positive and negative symptoms of schizophrenia. Nevertheless, a patient's level of functioning mainly influences the awareness of a decision. Thus, a psychotic patient can provide informed consent.

But how can we determine whether a patient can consent to participation in a trial? International practice has several instruments at its disposal, which make it possible for a patient to provide informed consent. MacCATCR semi-structured interview (MacArthur Competence Assessment Tool for Clinical Research) is one of them. It takes 15–20 minutes to conduct an interview and estimate the patient's ability to take decisions.

Moreover, there exist several short versions of similar interviews: Brief Assessment for Consentto Clinical Research (BACO) [30] and Evaluation to Sign Consent (ESC) [31]. Nevertheless, the questionnaires are not translated and validated in Russian.

Using the questionnaires, we can find a group of risk with a reduced ability to take decisions. And then we face a dilemma of what can be done with these patients. Non-inclusion of them into a trial violates their rights due to the lost potential profit.

As it was written previously, researchers had to use their own experience and opinion when dealing with this issue.

The researchers who participated in the CATIE (Clinical Antipsychotic Trials of Intervention Effectiveness) big project have solved the problem with the help of the so called 'test subject's assistant' [32]. The person controls a patient's ability to provide informed consent to participate in the project. Apart from assessment of this ability during inclusion into the trial, the assistant exerts control over the patient during the entire project and can initiate its exclusion from the trial when the status is changed. This important fact takes into account a chronic nature of mental disturbances and therapy duration, whereas many trials are conducted separately. That's why the patient's ability to take a decision can be changed significantly.

Some authors say that various educational interventions within a week considerably increase awareness of patients with mental disorders [23–34]. Different thematic presentations and/or computer programs were used during similar trials as educational activities.

Just like in any other area of medical research, non-inclusion deprives patients of potential benefit. When a patient is unaware of a possible risk, researchers are facing a huge ethical challenge.

Nowadays there is no single solution to the problem. However, the issue can be highlighted due to special attention given by a researcher to patients from a high-risk group, conduction of various educational activities which seem clear to the patient, and attraction of third parties who allow to perform independent external control.

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